

REMARKS

Entry of the foregoing election-of-invention and an early examination on the merits of all claims now pending in the above-identified patent application (i.e., Claims 18 and 35-51) are respectfully requested in view of the foregoing amendments and the following remarks.

The first Office Action for the instant patent application consisted solely of a restriction requirement, issued pursuant to 35 U.S.C. §121, requiring Applicant to elect among the following groups of invention:

Group A: Claims 1-17, drawn to a sensor;

Group B: Claims 18-26, drawn to a method of SaO₂ monitoring;

Group C: Claim 27, drawn to a method of SIDS monitoring;

Group D: Claim 28, drawn to a data collection system; and,

Group E: Claims 33 and 34, drawn to a data collection system.

Applicant has elected the claims of Group "B," i.e., the subject matter of original Claims 18-26, intended to recite a method of SO₂ monitoring, rather than "SaO₂" monitoring, and, by the present Response, has accordingly amended independent Claim 18 to correct, what is submitted to be, an obvious typographical error in the original text of Claim 18.

Specifically, independent Claim 18 has been amended to clarify that it is the total blood oxygenation (SO₂) that is to be monitored, as opposed to only arterial blood oxygenation (SaO₂). The amendment to the preamble of Claim 18 is being entered so that the preamble will properly conform to the body of the claim, to the Specification and to the main-stated purpose of the invention.

Subject matter support for the present amendment of Claim 18 is found in the Specification at Page 3, line 22 - Page 4, line 2, which states that:

"Generally the device and technique of the present invention measures oxygen saturation (SO₂) ie the value of oxygen saturation in venous and arterial tissue combined. Because oxygen saturation in venous tissue is usually low it is well known that the value of SO₂ is less than that of SaO₂. In the technique of the invention we call the difference the scaling factor Δ , such that

$$SaO_2 - SO_2 = \Delta$$

Thus the technique of the invention initially measures SaO₂ using a conventional arterial blood oxygen meter eg a pulse oximeter. SO₂ is then measured to determine and thus subsequently SO₂ measurements made using the device of the invention are corrected by the value of Δ ."

Emphasis added.

Consequently, the amendment now being entered to the preamble of independent Claim 18 attends to the correction of a clear typographical error.

The transition clause of Claim 18 has also been amended, for the purpose of conformance with U.S. claim practice, and now reads --comprising the steps of--.

The body of Claim 18 deletes the Greek symbol "delta" (Δ), since this symbol is not used in any subsequent claim and therefore provides no substantive limitation in the claims. Further, with respect to the scaling factor, Claim 18 has been amended to recite that it is used in a "correcting" step, which more closely conforms to the terminology used in the Specification (as quoted above), which refers to "corrected" by the value of the scaling factor (Δ).

Finally, Claim 18, as amended, also replaces the word "measuring" with the phrase "calculating an estimate of" SO_2 and adds the phrase "in blood to be monitored."

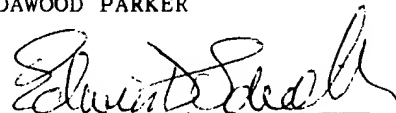
Applicant has further amended the claims by cancelling Claims 1-17 and 19-34, and has added new Claims 35-51. New Claims 35-39 are dependent upon independent Claim 18. Claims 40 and 45 are newly-presented independent claims, with Claims 41-44 and 46-51 being respectively dependent upon Claims 40 and 45. All claims now pending in the instant application recite alternative preferred embodiments of the inventive method for monitoring oxygenation and, consequently, are respectfully submitted to be within the scope of the elected invention, i.e., Group "B."

More particularly, pending Claims 18 and 35-51 all relate to a "single" invention falling under Group "B" and have been drafted to define the invention with greater clarity. As such, Applicant respectfully contends that all claims

recite a novel method for SO₂ monitoring. Such favorable action is respectfully requested and earnestly solicited.

Respectfully submitted,

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The Commissioner is hereby authorized to charge the Deposit Account of Applicant's Attorney, Account No. 19-0450, for any additional fees which may be due in connection with the prosecution of the present application, but which have not otherwise been provided for.

The amended equations in the Specification, at Page 6, lines 10 and 11, therefore correctly show the relationships, illustrated in Figures 2(a) and 2(b), and described in the text cited above, as the "sum of the moduli of the slopes of the lines connecting the isobestic points" and, consequently, do not add any new matter to the Specification.

The expression for calculating SO_2 at Page 6, line 15, of the Specification also contained a typographical error: The second " = " sign should be a multiplication sign, such as the asterisk (" * ") symbol commonly used in computer programming languages. Further, it is notoriously well known that to calculate a percentage, one takes a ratio and multiplies by 100 to obtain a percentage value from 0 to 100, instead of from 0.00 to 1.00. The amendment to the equation for calculating the percentage value of SO_2 in skin (Specification, at Page 6, lines 15-18) is corrected by this Response in such a manner.

In view of the foregoing election and amendments, Applicant respectfully requests an early examination on the merits and allowance of all claims (i.e., Claims 18 and 35-51) now pending in the above-identified patent application, which

now pending in the patent application should enable the Examiner to conduct a more focused and efficient search of the prior art and examination on the merits.

Applicant has also taken this opportunity to amend the textual Specification at Page 6 to correct the equations recited between lines 10-15 thereof, as explained below:

Referring to the Specification, at Page 10, line 26 - Page 11, line 8, which describe how "HbI" and "SO₂" are calculated:

"The two accompanying Figures illustrate how the HbI and SO₂ values are obtained from the spectra. HbI is the sum of the moduli of the slopes of the lines connecting the isobestic points as shown in the first Figure 2(a) . . .

"SO₂ values (Figure 2(b)) are calculated from the sum of the moduli of the slopes of the extinction values between the neighbouring isobestic points and the deoxygenated peak, normalised to the HbI value."

As the formula at Page 6, line 15, of the Specification indicates, OXI is an intermediate parameter used to determine SO₂.

Because of several typographical errors, the expressions for "HbI" and "OXI" at Page 6, lines 10 and 11, do not accurately represent the definitions found elsewhere in the text of the Specification. As is well known, the slope of a line is the change in the range variable ("y") divided by the change in the domain variable ("x"). Thus, according to the well known definition, slope = $\Delta y / \Delta x$. For a line segment,

the slope would, of course, be $(y_2 - y_1)/(x_2 - x_1)$, wherein (x_1, y_1) and (x_2, y_2) are the endpoints of the line segment.

In Figures 2(a) and 2(b) of Applicant's Specification, the range variable is the extinction value and the domain variable is the wavelength. The two equations that Applicant is now correcting are introduced at Page 6, lines 7-8, of the Specification as follows:

"The reflected absorptions (A) at six wavelengths (500, 528, 550, 560, 572 and 586 nm) are used to calculate two parameters HbI and OXI:"

The slopes of the line segments joining neighboring isobestic points of the curves shown in Figures 2(a) and 2(b) would therefore be $(A_{\lambda_2} - A_{\lambda_1})/(\lambda_2 - \lambda_1)$, where A_{λ_n} is the absorption value at isobestic wavelength λ_n .

It is also well known that the term "modulus" is the complex equivalent to the scalar "absolute value." For example, as the online mathematics resource "Mathworld" (maintained by the makers of the widely used mathematics software package *Mathematica*) states (<http://mathworld.wolfram.com/AbsoluteValue.html>):

"The absolute value, and more generally the complex modulus of a number z , is implemented in *Mathematica* as `Abs[z]`."

The modulus, that is, absolute value, of a line joining two neighboring isobestic points $(\lambda_2, A_{\lambda_2})$ and $(\lambda_1, A_{\lambda_1})$ is therefore properly written as:

$$|A_{\lambda_2} - A_{\lambda_1}|/(\lambda_2 - \lambda_1)$$